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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,611	07/22/2002	Martin Von Bergen	029976-0101	9060
22428	7590	09/07/2005	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			CHEU, CHANGHWA J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/070,611	BERGEN ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jacob Cheu	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28,29,33-41,47-51,54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-29, 33-41, 47-51, and 54-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*u*

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### **DETAILED ACTION**

Applicant's amendment filed on 7/7/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-27, 30-32, 42-46, 52-53 are cancelled.
2. Claim 55 is added to the instant application.
3. Currently, claims 28-29, 33-41, 47-51, and 54-55 are under examination.

### ***Claim Rejections - 35 USC § 112***

#### ***Written Description***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 33, 36-41, 48 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims meets the requirements for how to use the claimed method of identifying inhibitors of modifying the paired helical filaments (PHF) formation because the specification specifically teaches method of screening for inhibitors that inhibits the formation of PHF assembly and/or aggregation (See Example XIII). However, The specification describes assays for determining whether a given compound possesses certain desired characteristics and identifies some broad categories of compounds that might work, these descriptions without more precise guidelines amount to little more than a starting point, a direction for further research. Particularly, the specification merely documents two inhibitory peptides, namely G10 and F6 which can inhibit

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PHF formation at 200 uM to 50% and 30%, respectively. The claimed invention is drawn to a genus of inhibitor(s) identified by the method of claim 28, and the specification merely discloses these two examples of the structure compounds within the scope of what is claimed.

Nevertheless, structural identifying characteristics of the inhibitor genus are not disclosed. There is no evidence that there is any per se structure/function relationship between the disclosed inhibitor and any other that might be found using the claimed method. This situation is analogous to that of *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398. Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claims fail to comply with the written description requirement.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 28-29, 33-41, 47-51, and 54-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 28, step (a), it is not clear what "derived" means in the claim language. This term may denote meaning of chemical modification, mutation or some other means. It is suggested that applicant replaces or deletes this term. Similarly, claims 47, 49, 51 and 54 suffer the same problem.

With respect to claim 28, step (a), it is not clear what "defined" means in the claim language. Particularly, it is not clear whether it is an "open", such as "comprising", or "closed", such as "consisting of". Similarly, claims 37, 47, 50, 51 and 54 suffer the same problem.

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With respect to claim 47, step (a), “a peptide comprising are” is vague and confusing. It is suggested that applicant correct grammatical error to “a peptide comprising a specific tau derived peptide”.

With respect to claim 47, step (c), “a standard” is vague and indefinite. It is not clear what is the “standard” applicant refers to.

With respect to claim 54, it is suggested that applicant using term of “an isolated nucleic acid” for clarity.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 28-29, 33-41, 49-51, 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Wischik et al. (WO 96/30766).

Wischik et al. teach a method for identifying and obtaining an inhibitor capable of modifying the paired helical filaments (PHF) formation. Wischik et al. teach incubating a tau protein or its derivative peptide, i.e. SEQ ID No. 1 (comprising the instant elected SEQ ID No. 9) with a compound suspected of being capable of inhibiting the tau-tau association, e.g. PHF assembly, and detect the increase or decrease of the assembly of PHF as indicative of inhibitor of PHF formation. (See page 8, line 12-26; SEQ ID No. 1, Figures 6).

With respect to claim 34, Wischik et al. teach immobilizing peptide(s) on a solid phase (See claim 3).

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With respect to claim 35, Wischik et al. teach conducting the assay in a sodium chloride or salt or salt mixture condition (See claim 7).

With respect to claims 36-41, Wischik et al. teach that the tau protein can be recognized by monoclonal antibody at certain amino acid residues (page 6, line 11-25). The antibody can bind to the tau protein, comprising the SEQ ID No. 9. (See page 6, line 11-25). Wischik et al. teach that the tau-tau protein assembly inhibitor might be applicable for Alzheimer's disease (See page 1-2, Introduction).

With respect to claim 49-51 and 54-55, Wischik et al. teach using recombinant techniques to produce the tau peptide, i.e. SEQ ID No. 9, in E Coli cell culture system.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wischik et al. in view of Vandermeeren et al. (US 20030138972).

Wischik et al. reference teaches a method of identifying and obtaining an inhibitor capable of modifying the PHF formation by use of a peptide comprising SEQ ID No. 1( as recited SEQ ID No. 9 in instant invention) immobilizing on a solid support and incubating the SEQ ID No.1 peptide with potential compound(s) to determine its affect on the assembling of the PHF formation (See paragraph 4 in this Office Action). However, Wischik et al. do not explicitly teach using a kit to conduct the assay for screening potential candidates of PHF inhibitors. Vandermeeren et al. teach using a standard kit containing protein recognizing PHF-tau region as a convenient and economical tool for detecting neurological diseases (See section 0082, 0091, claim 15). Thus, one of ordinary skilled in the art at the time the invention was made would have been motivated to make a kit useful for the detection of an inhibitor capable of modifying the PHF formation because standard kits enhance the probability of the reproducibility and efficiency of the detection process.

### ***Response to Applicant's Arguments***

#### ***Wischik et al. reference (WO 9630766)***

Applicant's main argument focuses on that the instant invention using a specific peptide, i.e. SEQ ID No. 9 (8 amino acid) whereas the Wischik et al. using a larger fragment (90 amino acid fragment) for assaying the potential modulator of the PHF formation. Applicant's argument has been considered but is not persuasive.

Examiner agreed, *in part*, that the instant invention using a specific peptide to identify potential inhibitor capable of inhibiting the formation of PHF (emphasis added). As indicated in this Office Action on the rejections on 35 USC, 112, second paragraph, examiner points out the uncertainty of the term "defined" which could be interpreted as an open language, such as

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comprising. Furthermore, the language used by applicant in step (a), "incubating a peptide comprising a specific tau derived peptide" is also considered an open language. In essence, examiner takes the position to interpret the claim language as a broad "open" term, such as "comprising" which would encompass the specific SEQ ID No. 9.

If, assuming arguendo, a closed term is used, such as "consisting of", the reference of Wischik et al. would not anticipate the invention because as applicant demonstrates that Wischik et al. do not teach using a specific 8 amino acid peptide fragment to screen for potential inhibitors capable of inhibiting PHF formation. Accordingly, the rejection under Wischik et al. is maintained and deemed proper.

#### *Conclusion*

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Examiner  
Art Unit 1641



August 25, 2005



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08/29/05